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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,238	02/22/2006	Christopher John Montague Meade	1/1460 PCT	2614
28519	7590	02/16/2007	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/16/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/544,238	MEADE ET AL.	
Examiner	<b>Art Unit</b>		
David Lukton	1654		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 07 December 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-25 and 29-36 is/are pending in the application.  
4a) Of the above claim(s) 19,20,22,24,25 and 29-34 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-18,21,23,35 and 36 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date . . . .  
4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. . . .  
5)  Notice of Informal Patent Application  
6)  Other: . . . .

Claims 1-25, 29-36 remain pending. Applicants' response (filed 12/7/06) to the species election requirement is acknowledged:

- a ) the counterion of the tiatropium cation "includes" bromide ion;
- b ) the carrier (or excipient) is lactose;
- c ) the "form" of the elected composition is a powder;
- d ) in the elected composition, there is at least one particle present which has a diameter of 5 microns.

Applicants have argued that the size of the particles is not relevant to the issue of obviousness. If that represents applicants' actual views on the matter, then the foregoing election (of particle) size will be moot. But suppose, for purposes of discussion, that applicants were to submit the following claim:

*100. A powder according to claim 16, wherein the particles each have a diameter within the range of 1-5 microns.*

If this were rejected over a reference which disclosed a particle size range of 50-100 microns (and no other range), applicants' views on obviousness might then be different from what has been asserted in the paper filed 12/7/06. However, as indicated above, the matter of particle sizes will be moot unless applicants choose to make an issue out of it.

And to reiterate the previous response to the prior "election of species" requirement, the elected composition contains tiatropium (the anticholinergic), and the elected

composition also contains (as the TACE inhibitor) the compound of formula 2a wherein R<sup>1</sup> is OH and R<sup>2</sup> is isobutyl.

Claims 26-34 are withdrawn pursuant to the restriction; claims 19, 20, 22, 24, 25 are withdrawn because they do not encompass the elected species. Claims 1-18, 21, 23, 35, 36 are examined in this Office action.

\*

Claims 1-18, 21, 23, 35, 36 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, the term “TACE” may be used if accompanied by an explanation of what this abbreviation is intended to represent (presumably tumor necrosis factor-*alpha* converting enzyme).
- In claim 4, the cryptic terms “SL422”, “SO057”, “SC903” (etc.) may be used if accompanied by the chemical names (or structures) that these terms represent.
- Claim 12 asserts that a single composition is equal to two separate compositions, and that two separate compositions is equivalent to a single composition. However, this is at odds with conventional notions of proper English grammar and usage. If deemed appropriate, applicants could add an independent claim which is drawn to two separate compositions.

\*

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-5, 12-17, 35, 36 are rejected under 35 U.S.C. §103 as being unpatentable over Disse (US 2002/0193394) in view of Trifilieff, A. (*Br. J. Pharmacol.* **135**, 1655-1664, 2002).

Disse discloses that tiotropium is useful for treatment of COPD and asthma. Disse does not suggest combining tiotropium with a TACE inhibitor.

Trifilieff discloses that the TACE inhibitor PKF 242-484 [i.e., (2S,3R)-N-4-((S)-2,2-Dimethyl-1- methylcarbamoyl- propyl)-N-1-hydroxy-2-hydroxymethyl-3-(4- methoxy-phenyl)succinamide] is effective to treat COPD and asthma.

Thus, it would have been obvious to one of ordinary skill to combine the two agents for additive effects.



WO 02/072095 was stricken from the IDS because of the absence of a translation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER